



Dr. Robert Moore Division of Compliance and Enforcement/ONPLDS Center for Food and Safety and Applied Nutrition U.S. Food and Drug Administration HFS - 810 5100 Paint Branch Parkway College Park, MD 20740

Dear Dr. Moore:

Inverness Medical Nutritionals Group is launching a new dietary supplement and wishes to notify the Food and Drug Administration. The supplement, Triple Energy, consists of the active ingredients Panax Ginseng 100 mg, American Ginseng 100 mg, Eleutherococcus senticossus 100 mg, and will bear the following structure/function statements on the label(s).

Display Panel (Bottle Label)

Supports Physical and Mental Performance *

Side Panel (Bottle Label)

Ginseng and Eleutherococcus senticossus (formerly known as Siberian ginseng) have been used for centuries to maintain overall health and vitality. The ginsenosides in American and Panax ginsengs and eleutherosides in Eleutherococcus senticossus aid in the release of energy and are important for well-being and mental alertness. *

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

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Hang Tag

Feel the Energy!
Increase Mental & Physical Performance *

Ginseng and Eleuthero assist your body's response to physical and mental stresses. Triple Energy helps your body boost energy, which is helpful in performing physical activity. It also may help you recover from stresses by promoting a peaceful mental state.*

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Tray Label

Supports Mental & Physical Performance*

*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

We certify that the information contained in this notice is complete and accurate, and we have substantiation that the above structure/function statements are truthful and not misleading.

Sincerely,

William J. Neumann

Vice President

Quality and Regulatory Affairs